

10. (Amended) The method of claim 1 wherein the additional agent which exhibits progestogenic activity expresses both androgenic and progestogenic activity.

aa 2
11. (Amended) The method of claim 10 wherein the additional agent which exhibits progestogenic activity comprises the combination of an androgen and a progestin.

12. (Amended) The method of claim 10 wherein the additional agent which exhibits progestogenic activity is a single material which expresses both activities.

13. (Amended) The method of claim 12 wherein the additional agent which exhibits progestogenic activity is danazol or levonorgestrel.

aa 3
~~16. (Amended) The kit of claim 14 wherein the agent which exhibits progestogenic activity is an antiprogestin.~~

REMARKS

The grammatical error noted by the Examiner has been corrected above.

The Examiner's indication that claims 2-3 and 6-7 are allowable is noted with appreciation. It is respectfully submitted that all claims are allowable for the reasons set forth below.

Claims 1 and 14 were rejected under 35 U.S.C. § 102 and claims 4, 5, 8-13 and 16-20 under 35 U.S.C. § 103 over Garfield, et al. This rejection is respectfully traversed.

These rejections are clearly based on the statement on page 2 of the Office Action that "estrogens are considered clearly within the scope of the claims since they are selective for, and modulate, the estrogen receptor." It is respectfully submitted that this

statement is not relevant to the claims under consideration. The term "selective estrogen receptor modulator" is a term of art. As pointed out on page 4 of the application, a selective estrogen modulator constitutes those materials also known as a SERM, selective estrogen or anti-estrogen. Estrogen is not a "selective estrogen receptor modulator" as that term is understood in the art. ✓

The claims under consideration recite the combination of a SERM and progestin. Garfield et al. does not teach or suggest the combination of a SERM and progestin. Garfield et al. does not teach or suggest the use of a SERM for contraception. Quite to the contrary, the reference teaches that clomiphene, a known SERM, stimulates ovulation at col. 5, last three lines. ✓

The rejection of claims 14-20 under 35 U.S.C. § 103 over the combination of Tanaka, Poulin and Goodman Gilman is respectfully traversed. These references relate to hormonal dependent cancers. The Office Action acknowledges that the claims differ from the prior art in that they are drawn to kits for use in contraception, but state that an intended use will not render patentability towards claim drawn to a kit. It is respectfully pointed out that this characterization of claim 14 (and the claims dependent thereon) is much too broad. Claim 14 explicitly recites that the tablets in the kit contain an amount of SERM effective for contraception of a pre-menopausal female and that the progestogenic agent is present in an amount effective to modulate the side effects of the SERM. A kit containing such amounts is not taught or suggested by the combination of references. While the Office Action makes reference to optimization of amounts of agents being within the skill of the art, that assertion assumes, *sub silentio*, that the agents are being administered for the same purpose as the prior art. That, however, is not true in this instance. |

In light of all of the foregoing, it is respectfully submitted that this application is in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231, on November 8, 1999:

Edward A. Meilman

Name of applicant, assignee or
Registered Representative

Edward A. Meilman

Signature

November 8, 1999

Date of Signature

Respectfully submitted,

Edward A. Meilman

Edward A. Meilman

Registration No.: 24,735

OSTROLENK, FABER, GERB & SOFFEN, LLP

1180 Avenue of the Americas

New York, New York 10036-8403

Telephone: (212) 382-0700

EAM:mzl:mgs